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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/905,709	08/05/1997	DAVID STERN	52876/JPW/JM	5754

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COOPER & DUNHAM
1185 AVENUE OF THE AMERICAS
NEW YORK, NY 10036

EXAMINER

LAZAR WESLEY, ELIANE M

ART UNIT	PAPER NUMBER
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1646

DATE MAILED: 04/23/2002

24

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

08/905,709

Applicant(s)

Stern

Examiner

Eliane Lazar-Wesley

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Feb 6, 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-10, 12, 13, 15-27, 29, 30, and 32-46 is/are pending in the application.
- 4a) Of the above, claim(s) 40-45 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-10, 12, 13, 15-27, 29, 30, 32-39, and 46 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- *See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☒ Notice of References Cited (PTO-892) 18) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 19) ☐ Notice of Informal Patent Application (PTO-152)
- 17) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 23 20) ☐ Other:

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DETAILED ACTION

1. The amendment filed February 06, 2002, has been entered.

Claims 1-10, 12, 13, 15-27, 29, 30, 32-35, and new claims 36-46 are under consideration.

Newly submitted claims 40-45 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: claims 40-45 are to a method of preventing atherosclerosis which comprises administering an antibody or portion thereof capable of binding to RAGE. The invention originally claimed involved administering a polypeptide which comprises the V domain from the soluble receptor for AGE (sRAGE). These inventions are independent and distinct, as the methods use different agents having different structures and functions, and the searches are different and not co-extensive.

Claim 1 has been amended to recite administering "an agent" capable of inhibiting an interaction between AGE and RAGE. The invention originally claimed involved administering a polypeptide which comprises the V domain from the soluble receptor for AGE (sRAGE). These inventions are independent and distinct, as the methods use different agents having different structures and functions, and the searches are different and not co-extensive.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 40-45 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03. Claims 1-10, 12, 13, 15-27, 29, 30, 32-35 and 46 will be examined in part, as they apply to the originally presented invention.

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Claim Objections

Claim 1 and dependent claims 2-9, 15-18, 36-37 are objected to as reciting “an agent” capable of inhibiting an interaction between AGE and RAGE, which encompasses non-elected subject matter.

IDS

The Information Disclosure Statement (PTO 1449) filed March 12, 2002, has been received and considered.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 1-10, 12-13, 15-18, 36-39 and 46 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The claims are to a method of preventing atherosclerosis in a subject suffering from hyperlipidemia. However, “preventing” is an absolute word, and atherosclerosis depends on many risk factors, as discussed for example in Basha, Am.Heart J., June 1995, 131(6):1192-202, first and second column. Applicants is also referred to the rejection in the Office action mailed 6/24/99 (Paper#8), at page 5. Furthermore, hyperlipidemia includes different pathologies and different types

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of lipids involved (see again Basha). In view of the state of the art, that atherosclerosis has many causal factors and a variable course of development, and considering the lack of guidance and working example about, for example, the stage of the disease at which the administration should be implemented, and which population will be targeted, it is unpredictable if the method claimed will allow for prevention of atherosclerosis, and for which population, and the claims to a method of preventing atherosclerosis are not enabled by the specification.

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claim 6 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 6 is not further limiting claim 1. While amending claim 6, applicants must be aware that claims 7 and claims 36 and 37 must be further limiting the claim they depend from.

Priority

6. Applicant's claim for priority under 35 U.S.C. 120 is acknowledged. However, the applications 08/592, 070, filed January 26, 1996, and 08/755,235, filed November 22, 1996, upon which priority is claimed fail to provide adequate support under 35 U.S.C. 112 for the claims of this application. Applications 08/592,070 and 08/755,235 do not support claims to methods to prevent

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atherosclerosis, or to inhibit progression of a macrovessel disease, which comprise administering the V-domain of sRAGE.

The priority date for this application remains August 05, 1997, which is the filing date of application 08/905,709.

Applicants arguments have been considered but have not been found persuasive, because the parent applications do not contemplate the interaction of AGE and RAGE, and that reciting that "administering to the subject an agent capable of inhibiting the interaction of an amyloid β peptide with the receptor for advanced glycation end products treats "diabetes" and "hyperlipidemic atherosclerosis" does not provide support for the specific interaction involving soluble RAGE that is claimed. Furthermore, the originally claimed invention is not to a method using any inhibitor of receptor for AGE, but to a method using a specific domain of sRAGE.

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

8. Claims 1-10, 12, 13, 15-27, 29, 30, 32-39 and 46 remain or are rejected under 35 U.S.C. 102(e) as being anticipated by Morser, US Patent 5,864,018, for the reasons of record.

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The claims as examined (see page 2 of this Office action) are to methods which comprise administering a polypeptide comprising the V-domain of sRAGE or a derivative thereof capable of inhibiting the interaction of AGE and RAGE. Claim 1 has been amended to recite that the method applies to a subject suffering from hyperlipidemia.

Morser teaches peptides like the peptide of SEQ ID No:8, which block the interaction of AGE and sRAGE (col.6, lines 41-52 and col.7, lines 13-20). While Morser defines these peptides by their sequence, these peptides constitute in fact fragments of sRAGE of about 10 amino acids in length, located in the V domain of SRAGE (see attached). The peptides of Morser are derivatives of the V-domain of SRAGE, as the specification, at page 8, line 30+, recites that : “The polypeptide may be a derivative of soluble receptor for advanced glycation end products (sRAGE). The polypeptide may be a soluble extracellular *portion of a receptor* for advanced glycation end product...”. He teaches that the soluble peptides of the invention will comprise one or more of the Ig-like domains of the extracellular region of RAGE (col.5, lines 24-28), therefore the soluble extracellular domain (sRAGE), comprising one Ig V and two IgC domains, is envisioned . He teaches that these polypeptides are useful in treating or preventing disorders which result from excessive levels of AGEs (col.19, lines 1-24), in particular in diabetic microvasculopathy, occlusive vascular disorders and atherosclerosis. He teaches therapeutically effective amounts of the polypeptides , and methods of administration (col.19, line 48 continuing through col.20).

While claim 1 has been amended to recite that the method applies to a subject suffering from hyperlipidemia, claims 1-10, 12, 13, 15-27, 29, 30, 32-35 remain rejected, and the new examined

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claims 36-39 and 46 are rejected, because this disorder and the disorders in the metabolisms of glucose or lipids recited in claims 4-9, 22-26, and 36-37, are associated with atherosclerosis, diabetes or macrovessel diseases (see for example Basha, Am.Heart J., June 1995, 131(6):1192-202 cited as evidence, at page 1192, col. 1). Claims 12 and 29 are included in the rejection, as the polypeptides of Moser encompass a 10 kilodalton domain of sRAGE.

Please note that the peptides of SEQ ID No:18, 12, 13 and 5 are also fragments of sRAGE of about 10 amino acids in length, located in the V domain of SRAGE (see attached), able to block the interaction of AGE and sRAGE.

9. No claim is allowed.
10. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

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11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eliane Lazar-Wesley, PhD, whose telephone number is (703) 305 4059. The examiner can normally be reached on Monday-Friday from 9:30am to 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler, can be reached on (703) 308-6564.

Official papers filed by fax should be directed to (703) 308 4242. Faxed draft or informal communications with the examiner should be directed to (703) 308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

ELW

April 19, 2002

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**LORRAINE SPECTOR
PRIMARY EXAMINER**